PACKING AND STERILIZING A PEN IN A KIT

BACKGROUND OF THE INVENTION

[0001] The present invention relates to sterilized medical packaging. In particular, the present invention relates to packaging a sterilized writing instrument, such as a pen, and labels, which may be contained in a pen and label kit (PAL) kit.

[0002] One problem often encountered in modern medicine relates to the need to identify and correctly label medical devices and products in a sterile fashion. Such medical devices and products may include therapeutic agents, (i.e., saline infused with a medicine), tissue samples, blood samples, used medical implements, and other medically related devices and products. The use of a sterile pen in such environments can prevent infection that might otherwise occur due to handling of a non-sterile implement. Because pens are routinely used by medical personnel, the risk of unintended exposure to dangerous agents resulting from the use of a non-sterile pen has been identified as problematic in the medical field.

[0003] Similarly, using sterile labels may reduce the risk of exposure or contamination by dangerous agents in a sterile environment, or by health-care professionals wearing sterile gloves. In some instances, touching a seemingly innocuous label that is not sterile may put patients at risk of infection. Such risks may be overlooked by the medical professionals because of the common use of such labels and because such labels must be used to correctly identify certain objects and materials.

[0004] One approach to addressing this problem has been to provide sterile PAL kits or pens along with certain medical products, or alone, for use by medical personnel. Some traditional methods of sterilization may include heat, chemical dipping and/or ultrasonic treatment. These traditional methods of sterilization may cause problems when used in attempts to sterilize a pen and labels, as the heat may melt the pen and the label adhesive, chemical dipping may damage the pen and labels, and ultrasonic treatment may not be as effective as other processes in killing all dangerous agents.

[0005] Sterilization using EtO (Ethylene Oxide) gas effectively kills bacteria and has been used to sterilize medical products since the 1960's. In a typical EtO cycle, a product is placed in an air tight chamber from which the air can be evacuated. EtO gas is then pumped into the chamber for an extended period of time. Temperature (heat) and humidity are also part of the cycle to enhance the kill time. After a certain period of time, the chamber recycles and pulls the EtO out and replaces it with clean air, as EtO gas is harmful to breathe. EtO sterilization usually requires about a day to prepare for a cycle, a day to run through the sterilizer, and about a week to wait for sterilization confirmation using a Petri dish sample test, making the EtO sterilization somewhat time consuming and expensive. Another problem with sterilizing pens using EtO sterilization is that drawing a vacuum in a volume containing a pen may cause the pen to leak, creating a mess.

[0006] What is needed is a sterilized PAL kit that can be processed quickly, while minimizing losses due to damaged or leaking pens.

BRIEF SUMMARY OF EMBODIMENTS OF THE INVENTION

[0007] Embodiments of the present invention relate to packaging a writing instruments, such as a pen, including the steps of placing the writing instrument into packaging configured to be sealed such that the writing instrument is contained in a sealed portion of the packaging, sealing the package, and sterilizing the writing instrument and the package using gamma sterilization such that all portions of the writing instrument are sterilized. Gamma sterilization is effective at sterilizing all components of the PAL kit, including the interior of any pen cap or lid and even the ink inside of a pen. Similarly, gamma irradiating labels ensures that the labels, including any adhesive layer, are sterilized throughout.

[0008] In some embodiments, the packaging is an inner packaging, and the method further includes the steps of placing the sealed inner packaging into an outer packaging, placing at least one other item into the outer packaging, sealing the outer packaging such that the sealed inner packaging and the additional items are contained in a sealed portion of the outer packaging, and sterilizing the contents of the outer packaging. In some embodiments, EtO sterilization is employed.

[0009] Another embodiment of the present invention is directed to a kit that includes packaging, a writing instrument, and labels configured to be written on by a user with the writing instrument. At least the writing instrument is sealed in the packaging, and at least the packaging and the writing instrument are sterilized using gamma sterilization.

[0010] In some embodiments, the packaging may be inner packaging, the kit further including outer packaging and at least one other item. The writing instrument is sealed in the inner packaging. The labels, and the at least one other item are sealed in the outer packaging, and the outer packaging and the contents of the outer packaging are sterilized, such as by using EtO sterilization, for example.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] To further clarify the above and other aspects of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0012] FIG. **1**A is a top view of a PAL kit including a pen and labels in a package according to one embodiment of the invention;

[0013] FIG. **1**B is a top view of the PAL kit including a pen and labels in a package of FIG. **1**A according to one embodiment of the invention;

[0014] FIG. **2** is a view of a PAL kit including a pen in a package according to one embodiment of the invention;

[0015] FIG. **3** is view of a kit including a PAL kit and additional packaging and components according to one embodiment of the invention; and